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(54) **Improvements in intravascular devices**

(57) An intravascular device comprises a cannula 1 and a hub 2, said hub having a straight limb 3 for reception of an introducing needle (not shown), and a side limb 4 connected to a sinuous fine bore flexible tube 9 terminating in means 10 for connection to a source of fluid medicament. The flexible tube 9 preferably terminates in an injectable rubber diaphragm 11 through which intermittent injections may be administered.

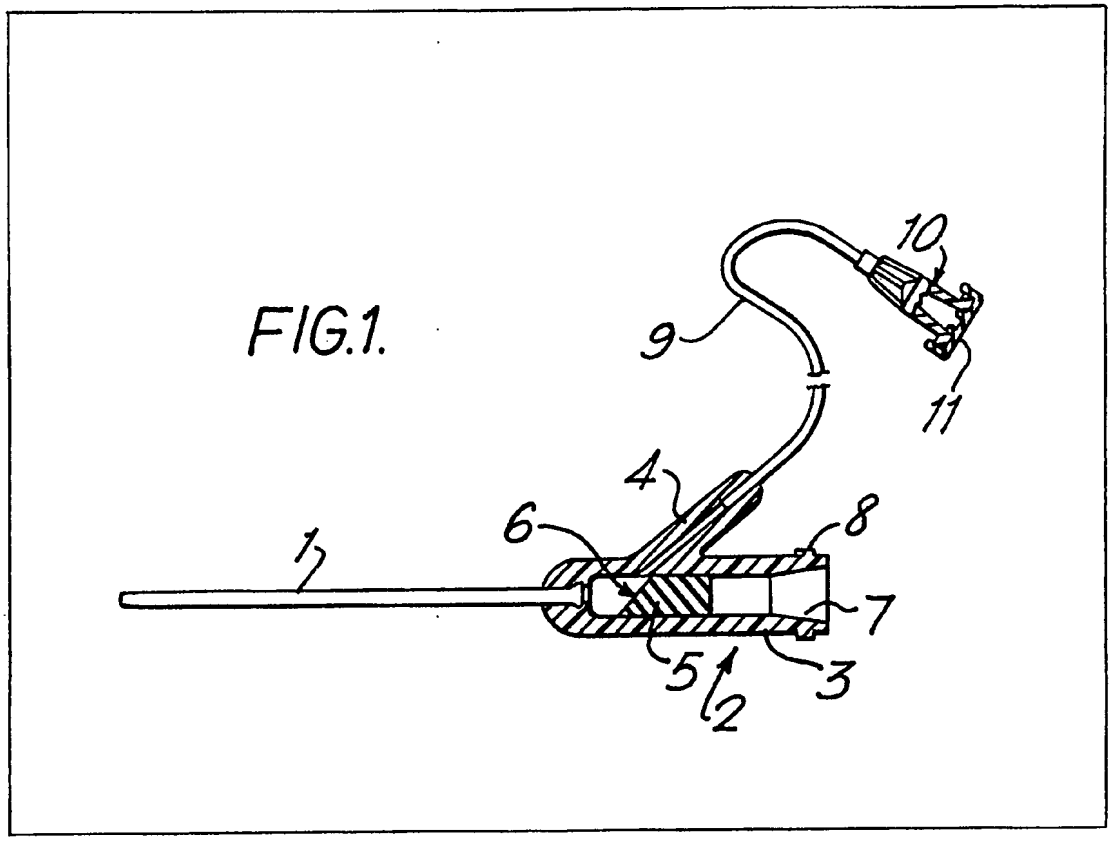

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FIG.1.

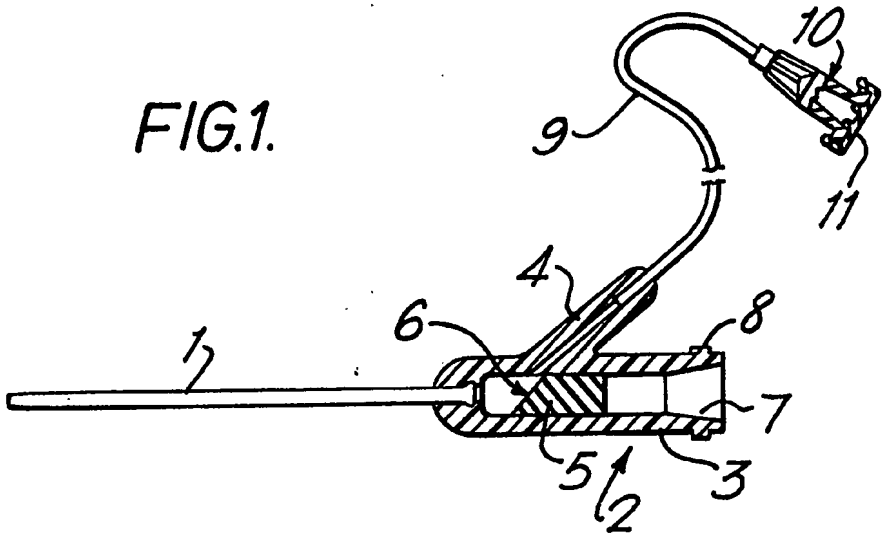


FIG.2.

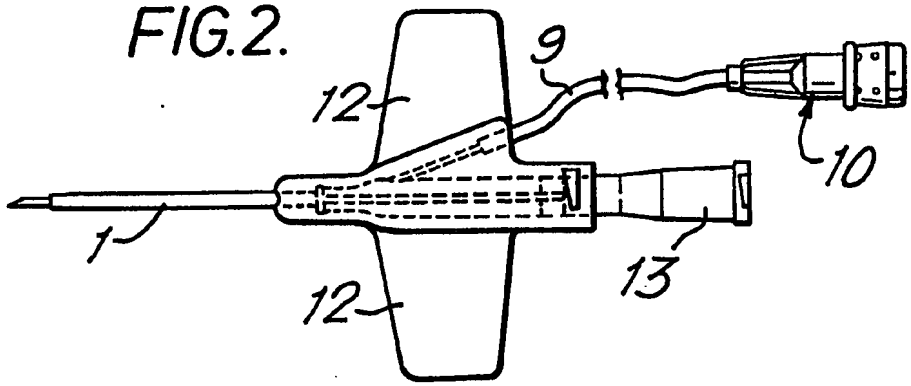
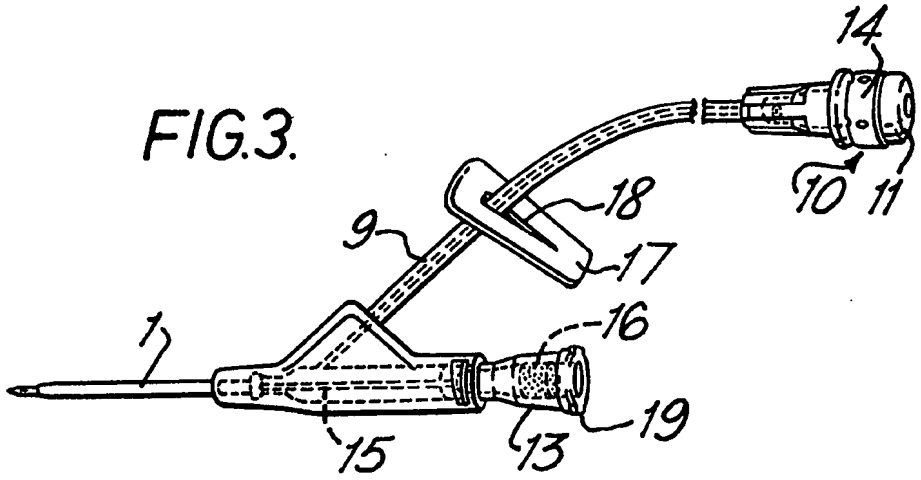


FIG.3.



SPECIFICATION

Improvements in intravascular devices

This invention concerns improvements in intravascular devices and more particularly concerns an improved two-way intravascular device.

It is customary to introduce a plastics cannula into a vein or artery by means of an introducing needle which, when withdrawn, leaves the cannula in situ to be coupled to equipment for supplying fluid for withdrawal or monitoring of blood.

A problem arises when it is desired to effect more than one procedure by means of a single cannula, for example when it is necessary to give repeated administration of drugs or to alternate drugs and fluid. A rubber self-sealing portion which is routinely fitted to infusion sets partially overcomes this problem. However when fluid is not required, intermittent administration of drugs must be made by a connection to the indwelling cannula, and this presents further problems. It is possible to fit an injectable diaphragm or non-return valve to the hub of the cannula, allowing intermittent injections. However it is a hazard to place such a multiple-use injection site close to the venepuncture site and close to the bedclothes, which are a common source of contamination in hospitals. There is a significant risk that the injection site will become contaminated, and that such contamination will be introduced into the patient.

When an injectable diaphragm is fitted to the hub of the cannular through which the introducing needle can be inserted, and the needle is withdrawn, the injectable diaphragm left in place can be used for the intermittent administration of drugs. However there is a "dead space" on the distal side of this diaphragm. In the intervening periods between injections, blood can coagulate in this dead space and the resulting blood clots can be propelled into the vascular system during the next injection. A further difficulty is that when a needle is left located through the diaphragm, it is common for back leakage to result.

It is also known to provide a cannula with an integral site for multiple injections but this has the same hazard of contamination mentioned above. Furthermore when the integral site is situated at any point distal to the cannula hub, a dead space results when fluid is not passing through the cannula and the same danger of clotting, discussed above, can arise. Such clots can of course present a serious hazard to critical areas of the circulatory system.

A further alternative available is a diaphragm fitted direct to an indwelling needle or an extension tube from the needle. This device carries the same hazards discussed above plus a further hazard of a sharp needle indwelling in a vein.

In one respect our invention provides an intravascular device comprising a cannula and a hub, said hub having a straight limb for reception of an introducing needle, and a side limb connected to a sinuous fine bore flexible tube terminating in means for connection to a source of fluid medicament.

The flexible, fine bore tubing which is connected to the side limb of the hub allows intermittent or continuous administration of drugs or fluid remote from the venepuncture site and from sources of contamination, i.e. the skin of the patient and the bedclothes. The fine bore of the tube minimises retention of administered drugs. Most suitably the bore is less than 1.5 mm, e.g. in the range 0.5 to 1 mm.

The flexible tube preferably terminates in an injectable rubber diaphragm having a surface which can be disinfected with a sterilising fluid. In one embodiment, the diaphragm is removable to expose a standard connector such as a luer/luer-lock record/record-lock or other tapered joint connector to mate with an infusion set or diagnostic equipment.

The flexible fine bore tube should be long enough to distance the injection site from sources of contamination, without being so long that it is impracticable. A length of at least 4 cm, e.g. 5—15 cm is generally suitable. The tube is preferably sealed non-detachably to the hub, e.g. by moulding the hub around it or by adhesive. Means may be provided to clamp off the tube, e.g. a sliding clamp having a tapered slot through which the tube passes.

For some applications it may be useful to provide two or more side limbs, each connected to a sinuous fine bore flexible tube terminating in means for connection to a source of fluid medicament. This embodiment permits simultaneous multiple administration of medicaments.

The straight limb of the device may be closed by a self-sealing elastomeric plug whose distal end terminates adjacent the junction with the side limb, thus effectively minimising the dead space in the hub.

The elastomeric plug, made e.g. of silicone rubber, is slightly compressed with the hub and seals tightly round the introducing needle. Moreover when the needle is withdrawn the plug is compressed shut and no leakage or ingress of contamination can take place. The device of our invention is also versatile in that when the elastomeric plug is omitted, suitable connection can be made to pressure monitoring equipment or the like. The straight limb, without the plug, may be coupled to e.g. a luer-lock fluid administration set. For this purpose the proximal end of the straight limb may be provided with ears or the like to engage with a male luer-lock, record-lock or other tapered joint connector.

When using the device of the present invention to give intermittent injections, a needle is not left in the patient's vein, thus minimising the risk of extravasation. The diameter of the cannula will vary in accordance with intended use, e.g. sufficiently small to be accommodated by the vein of a child patient, thus avoiding the need for special paediatric equipment.

The device has been found to be extremely useful in the surgical ward for intermittent injection of e.g. anaesthetic or antibiotics; for the management of acute emergency cases, e.g. the diabetic who needs a dextrose drip and insulin infusion from a syringe pump; for continuous infusion e.g. of heparin, using a syringe pump; for treatment of neonates and children; and for arterial pressure measurement. In the latter use, the pressure waveform may be monitored via the side tube and the straight limb used for flushing and sampling. The device is moreover extremely useful in experimental work and animal research.

The whole device may be made from suitable plastics materials. It is preferred that the hub is made of relatively soft flexible plastics material so that it causes less trauma to patients with delicate skin, e.g. children and burn cases.

Three embodiments of the invention are now described by way of example only with reference to the accompanying drawings.

Figure 1 illustrates an exemplary intravascular device in cross-section.

Figure 2 illustrates a modification of the device of Figure 1, in plan view.

Figure 3 illustrates a perspective view of a further modification.

The device of Figure 1 comprises a cannula 1 for insertion into a vein or artery and a hub portion 2. The hub comprises a straight limb 3 and a side limb 4. The straight limb 3 is closed by a solid plug 5 of silicone rubber whose proximal end 6 terminates adjacent the junction with the side limb 4. If desired the proximal end 6 may be angled as shown or rounded to reduce dead space still further; care must then be taken to insert the plug in the correct orientation.

The side limb 4 is joined to the fine bore tubing 9 having a bore about 1 mm and a length of about 75 mm. The tube 9 terminates in a female Luer lock hub 10 having a removable self-sealing diaphragm 11 which serves as the site for multiple injections. The surface of the diaphragm can be disinfected with a sterilising fluid. The diaphragm comprises a skirt which fits closely over the end of the hub and may be extended over the outside of the hub in a distal direction and locked with a shrink ring (see Figure 3). An annular projecting portion fitting tightly inside the hub improves the security still further.

Prior to the use of the device, the introducing needle has been inserted through plug 5 until its tip emerges from the distal end of cannula 1. The device is then placed in the body and the introducing needle is withdrawn. Plug 5 provides a fluid-tight seal at all times. Injections may then be administered through diaphragm 11 which can be located and protected in a clean site away from the patient's bedclothes.

When the diaphragm is removed, infusion fluids or the like may be administered through the fine bore tube 9 from a luer/luer-lock administration set, when a slow drip is required, or the hub 10 may be coupled to the nozzle of a syringe without needle.

Referring now to Figure 2, the device of Figure 1 has been modified by providing projecting webs or wings 12 to facilitate strapping of the device to the patient's body. Also shown is the needle hub 13.

In Figure 3 a device is shown without the plug 5. The web between the straight limb and side limb may be gripped conveniently during insertion, and after insertion may be turned down to lie against the patient's body, thus facilitating secure strapping of the device. The inserting needle 15 has a hub 13 which is a tight push fit into the straight limb of the device. After insertion into a patient's vein, the backflow of blood down the needle is visible through the transparent plastics material of hub 13, but spillage of blood is minimised by the filter member 16. For arterial cannulation, filter 16 is omitted and a syringe is connected to the needle hub 13. This procedure gives better control of arterial blood (which has a higher pressure than venous blood). The hub 13 has luer-lock ears 19.

The fine bore tubing 9 passes through a sliding clamp 17 having a tapered slot 18. The tube can be clamped off by wedging it into the narrow end of slot 18. The tube 9 terminates in a female luer/luer-lock hub 10, to which the self-sealing diaphragm 11 is secured by a removable shrink ring 14. The tube 9 has a length of about 60 mm. The distance between the diaphragm 11 and the central bore of the cannula hub is about 90 mm, and the dead space is only about 0.15 ml.

CLAIMS

1. An intravascular device comprising a cannula and a hub, said hub having a straight limb for reception of an introducing needle, and a side limb connected to a sinuous fine bore flexible tube terminating in means for connection to a source of fluid medicament.

2. A device according to claim 1 wherein said fine bore flexible tube has a bore in the range 0.5 to 1.5 mm.

3. A device according to claim 1 or 2 wherein said fine bore flexible tube has a length of at least 4 cm.

4. A device according to any of the preceding claims wherein said fine bore flexible tube terminates in an injectable rubber diaphragm.

5. A device according to claim 4 wherein said injectable rubber diaphragm is removable to expose a tapered joint connector.

6. A device according to any of the preceding claims wherein means are provided to clamp off said fine bore flexible tube.

7. A device according to claim 6 wherein said means comprises a sliding clamp having a tapered slot into which the tube may be wedged to clamp it off.

8. A device according to any of the preceding claims comprising two or more side limbs, each being connected to a sinuous fine bore flexible tube terminating in means for connection to a source of fluid medicament.

9. A device according to any of the preceding

claims wherein the straight limb of said hub is closed by a self-sealing elastomeric plug whose distal end terminates adjacent the junction with the side limb.

10. A device according to any of the preceding claims wherein the proximal end of the straight limb is provided with means to engage a tapered joint connector.

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